

## REMARKS

Claims 1-30 are pending. Claims 1, 11, 13, and 20 have been amended. No new matter has been introduced. Reexamination and reconsideration of the application are respectfully requested.

In the November 27, 2006 Office Action, the Examiner rejected claims 1, 3-5, 8-10, 20-21, 23-25, and 28-30 under 35 U.S.C. §102 (b) as being anticipated by Lamb, U.S. Patent No. 5,382,240 (hereinafter the Lamb reference). The Examiner rejected claims 11-14, 16, and 18 under 35 U.S.C. §102 (b) as being anticipated by Liu, U.S. Patent No. 5,931,815 (hereinafter the Liu reference). The Examiner rejected claims 1, 6, 15, and 26 under 35 U.S.C. §103 (a) as being obvious over Lamb or Liu in view of Tal (US2003/0153874). The Examiner rejected claims 2, 7, 22, and 27 under 35 U.S.C. §103 (a) as being obvious over Lamb or Liu in view of Maclean Crawford et al. U.S. Patent No. 6,659,984 (hereinafter the Maclean Crawford reference). The Examiner rejected claims 17 and 19 under 35 U.S.C. §103 (a) as being obvious over Liu in view of Lamb. These rejections are respectfully traversed.

### **Independent claim 1, as amended, recites:**

A telescopic winged safety needle assembly, comprising:

**a hub** having a distal end, a proximal end, and an axial through hole;

a cannula joined to said hub adjacent the distal end of the hub;

**a cylindrical sleeve** having a locking tab attached thereto, said cylindrical sleeve being axially disposed on said hub;

**a cylindrical sheath** for retaining said hub therein and having a distal end and a proximal end, said hub being slidable along an inner surface of said cylindrical sheath and an inner surface of said cylindrical sleeve from a first telescopic position at which

the distal end of said cannula joined to said hub projects beyond the distal end of said cylindrical sheath by a predetermined length, to a second telescopic position at which said distal end of the cannula is protectively contained within said cylindrical sheath, said cylindrical sleeve being axially disposed on said proximal end of said cylindrical sheath;

a pair of flexible wings provided on the outer peripheral surface adjacent the distal end of said cylindrical sheath; and

a first locking mechanism and a second locking mechanism disposed on said assembly, whereby said first locking mechanism releasably locks said hub, said cylindrical sleeve, and said sheath at the first telescopic position, and said second locking mechanism unreleasably locks said hub, said cylindrical sleeve, and said cylindrical sheath at the second telescopic position.

The Examiner rejected claims 1, 3-5, 8-10, 20-21, 23-25, and 28-30 under 35 U.S.C. §102 (b) as being anticipated by the Lamb reference. In so doing, the Examiner stated that "Lam discloses a cannula guard comprising a **hub (20)** with an axial hole therethrough, cannula (12) with a beveled edge (28), a **cylindrical sleeve (18)** capable of rotation within a **cylindrical sheath (22)** with openings (24), pair of flexible wings (26), connection tubing (14) and first and second locking system (Figures 1-8).

Wherein the locking mechanism comprises a two part system that releaseably locks the sheath into a first position and unreleasably locks the sheath into a second position (Figures 1-8) via several annular rings/ribs (for the sheath to slide over) and locking lugs that include angled edges and solid face edges to achieve the sheath locking capability.

The locking tabs are attached with a hinge type member to allow movement (emphasis added)."

The Lam reference states that “the needle 12 is attached to the tube 14 at a neck 16. The section of the needle 12 adjacent the neck 16 is coated or otherwise molded, such as through an insert- or injection-molding process, with a plastic or other suitable annular layer 18. A preferred material for this coating is polypropylene, although any of a wide variety of materials may be utilized with efficacy. Various structural features of the outer surface of the coating 18, and the utility thereof, are discussed below.

In an alternative embodiment, the annular coating 18 may constitute a **first tubular member 18**, with the needle 12 operably affixed to a **first end 20** of the tubular member 18, and the neck 16 constituting a second end of the tubular member 18. In such an alternative embodiment, the cannular means 12 does not extend through the length of the cannula guard assembly 10, but instead terminates in an intermediate portion thereof.

A **second tubular member such as a sheath 22** is slidably disposed about the cannular means 12 and preferably in contiguous relationship with the coating 18. The sheath 22 may be fabricated from polypropylene, polyethylene or some other suitable material. The sheath includes an opening 24 along one side thereof.” (Col. 3, lines 42-65, emphasis added).

The Lam reference further states that “the inner cannular needle 12 and its coating or **tube member 18** is slidingly displaced with respect to the **outer sleeve or sheath 22.**” (Col. 3, lines 42-65, emphasis added).

Referring to Figure 3 and Figure 6 of the Lam reference, the cannula guard assembly 10 is shown to include a cannular needle 12, a **tube member 18** (a hub), a **first end (20) of tubular member 18**, and a **sheath 22**. There is no corresponding

structure for the **cylindrical sleeve** shown in the Lam reference.

In the Office Action, the Examiner incorrectly identifies “a **hub (20)** with an axial hole therethrough, cannula (12) with a beveled edge (28), a **cylindrical sleeve (18)** capable of rotation within a **cylindrical sheath (22)**”. As shown in Figure 3 and Figure 6, the item 20 is the first end of the tubular member 18 and not the hub, the tubular member 18 is the hub, the sheath 22 is a sheath, and there is no corresponding structure for the **cylindrical sleeve** shown in the Lam reference.

The Lam reference does not disclose, teach, or suggest the telescopic winged safety needle assembly specified in independent claim 1, as amended. Unlike the telescopic winged safety needle assembly specified in independent claim 1, as amended, the Lam reference does not show “ a **hub** having a distal end, a proximal end, and an axial through hole; a cannula joined to said hub adjacent the distal end of the hub; a **cylindrical sleeve** having a locking tab attached thereto, said cylindrical sleeve being axially disposed on said hub; a **cylindrical sheath** for retaining said hub therein and having a distal end and a proximal end, said hub being slidable along an inner surface of said cylindrical sheath and an inner surface of said cylindrical sleeve from a first telescopic position at which the distal end of said cannula joined to said hub projects beyond the distal end of said cylindrical sheath by a predetermined length, to a second telescopic position at which said distal end of the cannula is protectively contained within said cylindrical sheath, said cylindrical sleeve being axially disposed on said proximal end of said cylindrical sheath”.

Accordingly, Applicant respectfully submits that independent claim 1, as amended, distinguishes over the above-cited reference. Claims 2-10 all depend directly or indirectly from independent claim 1, as amended. Therefore, Applicant respectfully

submits that claims 2-10 distinguish over the above-cited reference for the same reasons as set forth above with respect to independent claim 1, as amended.

Independent claim 20, as amended, recites limitations similar to independent claim 1, as amended. Specifically, independent claim 20, as amended, recites “a **hub** having a distal end, a proximal end, and an axial through hole; a cannula joined to said hub adjacent the distal end of the hub; a **cylindrical sleeve** axially disposed on said hub; a **cylindrical sheath** for retaining said hub therein and having a distal end and a proximal end, said hub being slidable along an inner surface of said cylindrical sheath and an inner surface of said cylindrical sleeve from a first telescopic position at which the distal end of said cannula joined to said hub projects beyond the distal end of said cylindrical sheath by a predetermined length and said assembly is minimized in length, to a second telescopic position at which said distal end of the cannula is protectively contained within said cylindrical sheath and said assembly is maximized in length, wherein said hub is pulled in a proximal direction relative to said cylindrical sheath and said cylindrical sleeve at said first telescopic position until said cylindrical sheath unreleasably locks to said cylindrical sleeve, followed by said hub unreleasably locking to said cylindrical sleeve at said second telescopic position”. Therefore, independent claim 20, as amended, also distinguishes over the above-cited reference.

Claims 21-30 all depend, directly or indirectly, from independent claim 20, as amended. Therefore, Applicant respectfully submits that claims 21-30 distinguish over the above-cited reference for the same reasons as set forth above with respect to independent claim 20, as amended.

The Examiner rejected claims 11-14, 16, and 18 under 35 U.S.C. §102 (b) as being anticipated by the Liu reference. In so doing, the Examiner stated that “Liu

discloses an infusion set comprising a *hub (31)* with an axial hole therethrough, a cannula (32) with a beveled edge (3A), flexible wings (43), connection tubing (2), a *cylindrical sleeve (1)*, a *cylindrical sheath (40)* for retaining the assembly therein in which the hub, sleeve and sheath are capable of being rotated in relation to each other (Figure 1) (emphasis added)."

The Liu reference states that "the infusion set of the present invention includes a **connecting tube 1** having an upper and a lower engaging sections 11, 12 around the outer periphery. The bottom end of the connecting tube 1 is connected with an infusion tube 2, while the top end thereof is connected with an **injection needle 3**. A **wing-equipped sheath 4** is slidably fitted around the connecting tube 1. The sheath 4 has a fitting hole 41. The wall of the fitting hole 41 is formed with a connecting section 411 for slidably engaging with the upper and lower engaging sections 11, 12 of the connecting tube 1. When the connecting section 411 of the sheath 4 is engaged with the upper engaging section 11, the injection needle 3 is retracted and hidden in the fitting hole 41 of the sheath 4 without protruding outside so as to avoid accidental impalement of other people." (Col. 2, lines 16-30, emphasis added).

The Liu reference states that "a second coupling section 14 is formed at the top end of the tube body 10 for fitting with a **needle seat 31** of bottom end of the **injection needle 3**" (Col. 2, lines 40-42, emphasis added).

Referring to Figure 1 of the Liu reference, the infusion set is shown to include a **injection needle 3** with a **needle seat 31** of bottom end of the injection needle 3, **connecting tube 1** (a hub), and a **wing-equipped sheath 4**. There is also no corresponding structure in the Liu reference for the **cylindrical sleeve** of the present invention.

In the Office Action, the Examiner incorrectly identifies item 31. As shown in Figure 1, the item 31 is the **needle seat 31** of bottom end of the injection needle **3** and not the hub of the present invention. There is also no corresponding structure in the Liu reference for the **cylindrical sleeve** of the present invention.

The Liu reference does not disclose, teach, or suggest the telescopic winged safety needle assembly specified in independent claim 11, as amended. Unlike the telescopic winged safety needle assembly specified in independent claim 11 as amended, the Liu reference does not show “a **hub** having a distal end, a proximal end, and an axial through hole; a cannula joined to said hub adjacent the distal end of the hub; a **cylindrical sleeve** having a locking tab attached thereto, said **cylindrical sleeve** being axially disposed on said **hub**; a **cylindrical sheath** for retaining said hub therein and having a distal end and a proximal end, said **hub** being slidable along an inner surface of said cylindrical sheath and an inner surface of said cylindrical sleeve from a first telescopic position at which the distal end of said cannula joined to said hub projects beyond the distal end of said cylindrical sheath by a predetermined length, to a second telescopic position at which said distal end of the cannula is protectively contained within said cylindrical sheath and said assembly is maximized in length, said cannula joined to said hub being rotateable relative to said cylindrical sleeve and said cylindrical sheath”.

Accordingly, Applicant respectfully submits that independent claim 11, as amended, distinguishes over the above-cited reference. Claims 12-19 all depend, directly or indirectly, from amended independent claim 11, as amended. Therefore, Applicant respectfully submits that claims 12-19 distinguish over the above-cited reference for the same reasons as set forth above with respect to independent claim

11, as amended.

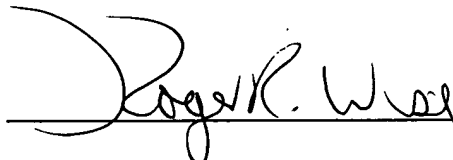
Applicant believes that the foregoing amendment and remarks place the application in condition for allowance, and a favorable action is respectfully requested. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance should the examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

PILLSBURY WINTHROP LLP

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By: \_\_\_\_\_



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